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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,178	10/17/2001	Jack Rogers	7570/73272	3914

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,178	Applicant(s) ROGERS, JACK	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately* in the "Sequence listing" and *in the text of the description* and claims whenever described. In other words, Figure 1 on page 4 of the specification needs to be amended to indicate the appropriate SEQ ID NOs described. See MPEP 2422 & 2431. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as nonresponsive, and may result in abandonment of this application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 7a-e & 12a-e, drawn to peptides comprising SEQ ID NO: 1, and compositions thereof, classified in class 530, subclass 324.
- II. Claims 6-7f & 12f, drawn to drawn to peptides consisting of SEQ ID NO: 7, and compositions thereof, classified in class 530, subclass 326.
- III. Claim 8a-e, drawn to an antibody generated toward a peptide comprising SEQ ID NO: 1, classified in class 530, subclass 387.1.
- IV. Claim 8f, drawn to an antibody generated toward a peptide consisting of SEQ ID NO: 7, classified in class 530, subclass 387.1.

- V. Claims 9-11a-e, drawn to polynucleotides encoding a peptide comprising SEQ ID NO: 1, vectors and host cells, classified in class 435, subclass 325.
- VI. Claims 9-11f, drawn to polynucleotides encoding a peptide consisting of SEQ ID NO: 7, vectors and host cells, classified in class 435, subclass 325
- VII. Claims 13-16a-e, drawn to a method of treating patients with a peptide comprising SEQ ID NO: 1, classified in class 514, subclass 12
- VIII. Claims 13-16f, drawn a method of treating patients with a peptide consisting of SEQ ID NO: 7, classified in class 514, subclass 13.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-VI are directed to products that are physically and functionally distinct, involving peptides, antibodies and polynucleotides to distinct and unique SEQ ID NOs, which possess their own unique structure and/or function. All of these products can be prepared by different processes, such as through chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the polypeptides of Group I and antibodies of Group II are fundamentally different molecules than the polynucleotide molecules of Group III, which in turn can be used to clone the protein, make vaccines, or used as therapeutic agents in gene therapy. Although the antibodies of Group II can be used in isolating

the polypeptides of Group I, the antibodies of Group II can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The polypeptides of Group I can be utilized in making the antibodies of Group II, but not vice versa. Additionally, neither the polypeptides of Group I nor antibodies of Group II require the vectors and host cells of Group III, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Inventions I-II and VII-VIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptides of Groups I & II can be used to generate antibodies, used in affinity chromatography, or used in materially different methods, such as to detect disease states related to oxidative damage. The methods of treating patients with the polypeptides in Groups I or II require patients and administration protocols that are not required in Groups I and II. It is noted that the methods of Groups VII-VIII do not require the products of Groups III-VI, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups VII-VIII are directed to methods of treating patients suffering from oxidative-induced damage through administration of structurally distinct polypeptides. Each of the methods requires physically and functionally distinct elements, which differ in the pharmaceutical composition to be administered. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. Note that *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product.

Art Unit: 1647

In situations where product and process claims drawn to independent and distinct inventions are presented in the same application, an applicant may be called upon under 35 U.S.C. §121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, when a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined. Withdrawn process claims not commensurate in scope with an allowable product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternative Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

January 13, 2004

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